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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,389	05/25/2001	Jacob Richter	2390/49704	1194
7590 DOROTHY R. AUTH CADWALADER, WICKERSHAM & TAFT LLP ONE WORLD FINANCIAL CENTER NEW YORK, NY 10281			EXAMINER BUI, VY Q	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 07/21/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/864,389

**Applicant(s)**

RICHTER ET AL

**Examiner**

Vy Q. Bui

**Art Unit**

3773

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 6, 8, 11, 26, 28, 31-47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 31-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6, 8, 11, 26, 28, 31-47 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

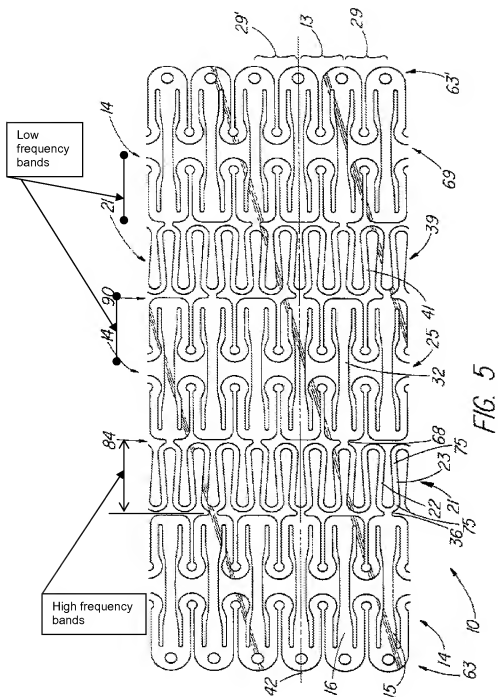
- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

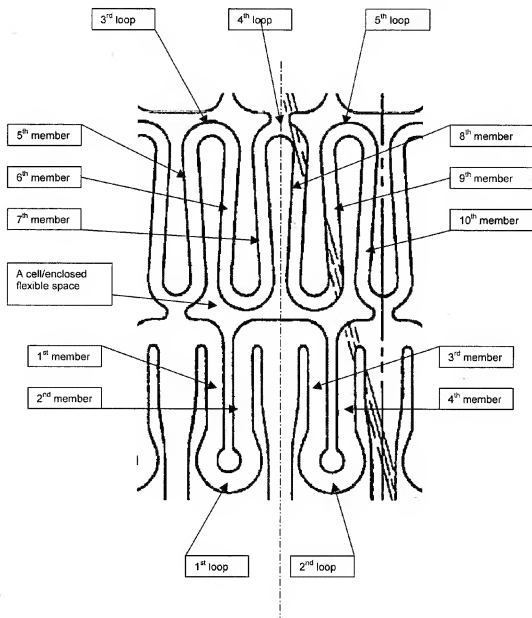
**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

DETAILED ACTION



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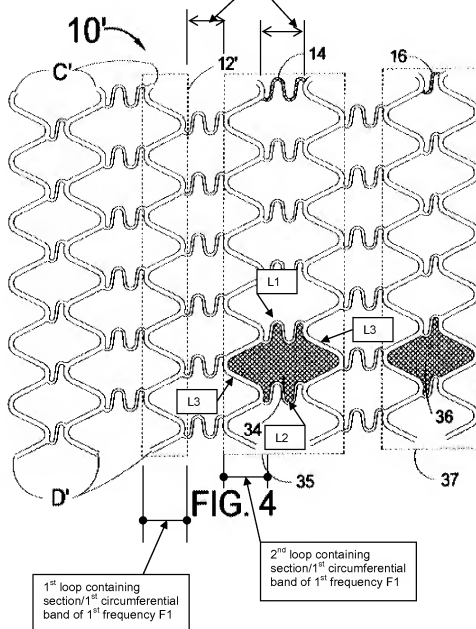


A cell in Fig. 5, BERRY et al.

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**Notes:**L1= 1<sup>st</sup> loop containing section of frequency F1L2= 2<sup>nd</sup> loop containing section of frequency F1L3= 3<sup>rd</sup> loop containing section of frequency F2 < F1

3<sup>rd</sup> loop containing section/2<sup>nd</sup>  
circumferential band of 2<sup>nd</sup>  
frequency F2 > F1



Fischell-6,190,403

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1, 6, 11, 42-47 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell (6,190,403).

Please refer to Fischell'-403's Fig. 4 reproduced and shown in page 4 of this "Office Action".

**1.1. As to claims 1, 6, 42-47 and 49**, Fig. 4 shows 1<sup>st</sup> loop containing sections/1<sup>st</sup> circumferential bands of frequency F1, 2<sup>nd</sup> loop containing sections/1<sup>st</sup> circumferential bands of frequency F1, and elements 14 as 3<sup>rd</sup> loop containing sections/2<sup>nd</sup> circumferential bands of frequency F2 being higher than F1 (F2>F1) extending in longitudinal, circumferential and radial directions of the stent 10' because they are 3-dimensional elements. Therefore, elements 14 indeed extend about a circumferential axis AA of stent 10' as recited in the claim.

Fig. 4 of Fischell'-403 clearly shows elements 14 having a width smaller than a width of 1<sup>st</sup> loop containing sections/1<sup>st</sup> circumferential bands of frequency F1 and 2<sup>nd</sup> loop containing sections/1<sup>st</sup> circumferential bands of frequency F1.

Further, Fig. 4 of Fischell-'403 clearly shows 1<sup>st</sup> loop containing sections of frequency F1 and 2<sup>nd</sup> loop containing sections of frequency F1 are out of phase 180 degrees.

**1.2. As to claim 11,** F. 4 of Fischell-'403 (see F. 4 reproduced above) show "triangular" cell 34 including elements 14 as 1<sup>st</sup> loop containing sections of frequency F1 and 2<sup>nd</sup> loop containing sections of frequency F1 define a 1<sup>st</sup> generally sinusoidal pattern, 3<sup>rd</sup> loop containing sections of frequency F2 ( $F2 < F1$ ) defines a 2<sup>nd</sup> generally sinusoidal pattern and a first junction end (also an adjacent 3rd loop containing sections along the stent) as recited in the claim.

Notice that cell 34 can be considered as triangular because at least 3<sup>rd</sup> loop containing sections and first junction end have a triangular configuration.

Further, loops in one 3<sup>rd</sup> loop containing sections of 2<sup>nd</sup> sinusoidal pattern are 180-degree out of phase with the adjacent second sinusoidal pattern along the stent.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 3, 8 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (6,190,403) as applied to claims 1, 6 and 26 above, and further in view of YANG et al (6,120,847).

As to claims 3, 8 and 28, Fischell-'403 discloses substantially all limitations recited in the claims, except for the stent is coated with a medicine for treatment purpose. However, coating a stent with a medicine or drug is well known in the art. For example, YANG discloses a method for coating a therapeutic substance on the surface of the stent for local treatment of a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a medicine coating to Fischell-'403 stent so as to have the medicine distributed directly to the treatment site of a blood vessel.

2. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al.-6,231,598.

Berry-'598 discloses substantially all limitations recited in the claims, especially critical cells structured as recited in the body of the claim (see a portion of Berry-'598's Fig. 5 showing a cell reproduced on page 3 above) including wider members and narrower members of the cells, wherein the narrower elements are for flexibility and wider elements are for radial strength to support a blood vessel, except for Berry-'598 stent also includes other cells (page 2 above). However, the cells as recited in the claim and as disclosed by Berry-'598 (as shown on page 4) are essential structures for the Berry-'598 stent as well as for the stent of the present invention. It would have been obvious to one of ordinary skill in the art to have other cell structures in combination with the cell structure as recited in the body of the claim, because the cells as recited in the body of the claim is essentially important.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11, 26 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1:

- Line 3, "the circumferential direction" lacks antecedent basis.

Claim 11:

- line 4, "the circumferential direction" lacks antecedent basis.

Claim 49: line 4, the recitation "... the circumferential direction" lack antecedent basis.

Amendment of the claim 49 is required.



***Response to Amendment***

Applicant's arguments filed 5/5/2008 have been fully considered but they are not persuasive.

**Rejection 102(e) based on Fischell-6,190,403:**

1. Arguments: as to claim 1, the applicant argued (page 12, Remarks, paper 5/5/2008) that "Applicants respectfully disagree and assert, as presented in the response dated September 28, 2007, that the links illustrated by Fischell Fig. 4 are not formed of a "single, continuous, generally sinusoidal pattern..., extending in a continuous band of loops around the circumference of the stent," as required by the instant claims" and similar arguments for claim 11.

Response: as to claims 1 and 11, element 14 as shown in Fig. 4 of Fischell-'403 is clearly qualified for the limitation "single, continuous, generally sinusoidal pattern..., extending in a continuous band of loops around the circumference of the stent" as recited in the claims of the present invention. Notice that element 14 of Fig. 4 of Fischell-'403 is indeed extending in a continuous band of loops around the circumference of the stent. The claim language requires element 14 extending around (a portion) of the circumference of the stent and does not require element 14 extending a whole circumference of the stent.

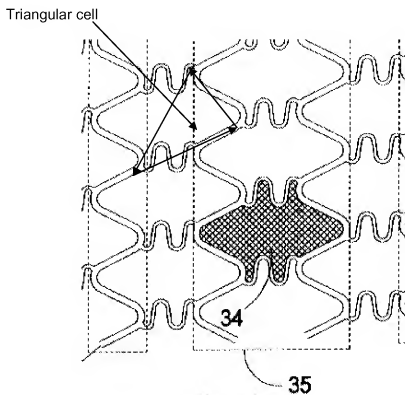
2. Arguments: as to claim 1, the applicant argued that Fischell-'403 does not form "a uniform pattern of flexible cells" (page 14, paper 5/5/08) and as to claim 11, the applicant argued (pages 15-16, paper 5/5/08) that "In addition, the Examiner has taken the position that Fischell Fig. 4 shows "triangular" cells formed by first, second and third loop containing sections

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as recited by Claim 11. Applicants respectfully disagree on the basis that the definition of a "triangular cell" is provided in the Specification at page 17 as "cells... of the present invention, which have three points" where the patterns connect.", and further shows an example of a triangular cell as shown in Fig. 10 of the present invention.

Response: as to claim 1, Fischell-'403 does show many cells having same configuration. Therefore Fischell-'403 does form "a uniform pattern of flexible cells" (please see below) as recited in claim 1.

As to claim 11, following a written description of a triangular cell as indicated above, here is a triangular cell in Fischell:

**FIG. 4**

**Rejection 103(a) based on Fischell-6,190,403 in view of Yang-6,120,847:**

The arguments of the Applicant based on the same arguments for 102(e) rejection based on Fischell-403. Therefore, the same responses are again applicable as mentioned above.

**Rejection 103(a) based on Berry-6,231,598:**

The Applicant argued (please see pages 21-22) that "Applicants respectfully disagree with the Examiner's position that Berry discloses substantially all limitations recited in Claim 26 of the present application. Claim 26 recites a stent "consisting essentially of a uniform pattern of flexible cells," wherein "each of the flexible cells .... consists essentially" of ten members that form a uniform pattern of flexible cells."

However, Berry-'598 does consist "essentially of a uniform pattern of flexible cells" as recited in the claim. Notice that the uniform pattern consists of a combination of two types of cells and each cell essentially consists of ten members dependent on a way a person of ordinary skill in the art would like to count.

**Rejection 112 2<sup>nd</sup> paragraph:**

Two different helical lines of a tubular body define two different circumferential directions. Therefore, inherently there are many circumferential directions in a stent. Without an antecedent basis, the recitation "the circumferential direction" is therefore not inherently unique.

### ***Conclusion***

This is a RCE of applicant's earlier Application No. 09/864389. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/s/ Vy Q. Bui/

Primary Examiner, Art Unit 3773